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(54) Benævnelse: **Elektrokemisk sensor til bestemmelse af en analytkoncentration**

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DESCRIPTION

Electrochemical sensor for determining an analyte concentration

Technical area

The invention relates to an electrochemical sensor for determining a concentration of at least one analyte in a medium, in particular a body tissue and/or a bodily fluid, moreover an apparatus in which the electrochemical sensor is used, a use of the electrochemical sensor and the apparatus and a method for producing the electrochemical sensor. Such sensors or apparatus are used in particular in the field of medical technology, for example in order to determine electrochemically a concentration of glucose (in particular blood glucose or glucose in a tissue fluid), lactate or other analytes, in particular metabolites.

Prior art

The determination of the blood glucose concentration and an appropriate medication is an essential part of the daily routine for persons with diabetes. The blood glucose concentration is quickly and easily determined several times a day, typically 2 to 7 times, in order to be able to take appropriate medical measures if necessary. In many cases, this involves a modification by means of automatic systems, in particular with insulin pumps.

In order to avoid restricting the daily routine of the person with diabetes any more than absolutely necessary, appropriately mobile devices are often used, which should be easy to transport and handle, so that a measurement of the blood glucose concentration, at work or in leisure time, for example, can be done easily.

At present, various mobile devices are available, which operate to some extent with different measurement methods and using different diagnostic methods. A first measuring method is based, for example, on an electrochemical measuring method, wherein a blood sample, which is taken from the patient's body tissue by

perforating a skin layer by means of a lancet, is applied to an electrode coated with enzymes and mediators. Appropriate test strips for such electrochemical measuring methods are described, for example, in US 5,286,362. Other known measuring methods use optical measuring methods, which are based, for example, on the fact that the substance to be detected (analyte) can react with certain detection reagents, wherein a colour change of the reaction mixture occurs. Systems for detecting such colour reactions and thus detecting the corresponding analytes are known from CA 2,050,677.

The described detection methods are predominantly based on the patient first extracting an appropriate sample of the bodily fluid to be tested, which can be both a blood sample and a urine sample and can then be tested accordingly by means of the test apparatus. However, this method has several disadvantages. For example, this process is extremely laborious and requires several handling steps. Thus, for example, a lancet must be provided and tensioned, then a skin layer must be perforated by means of this lancet, then a blood drop produced in this way must be applied to a test strip and then this test strip must be evaluated by means of an appropriate device. For many patients, especially the elderly and children, these steps are often difficult to accomplish because patients are limited in their motor skills and visual acuity, for example. Furthermore, it is possible only in few cases for these procedure steps to be carried out discreetly, so, for example, protection of the patient's privacy in the case of measurement at the workplace is not sufficiently ensured. Also, an incorrect operation in the measurement process can easily lead to false readings, with sometimes fatal consequences of incorrect medication based on false measurement results.

From the prior art, systems are therefore known which continuously generate measurement data and which can be used as an alternative or in addition to the systems or methods described above, for example in order to reduce the number of individual measurement operations. For example, systems are commercially available which include a membrane tube in the subcutaneous tissue through which a transport fluid is pumped. Glucose diffuses into the transport fluid via the membrane, which is in turn transported to an electrochemical measuring cell. The

glucose concentration is then measured in the electrochemical measuring cell. However, a disadvantage of such an arrangement for the continuous generation of measured values is that in this case the patient constantly must carry along a supply of transport liquid as well as an appropriate waste container for receiving contaminated transport liquid.

Other sensor types known from the prior art for continuous measurement generation are designed to be implanted in a body tissue. For example, US 6,892,085 B2 discloses an encapsulated glucose sensor system comprising a glucose sensor and a protective capsule. In this case, three electrodes, a working electrode, a counter electrode and a reference electrode are provided, which are applied to one side of a substrate. For better implantability, this electrode arrangement is incorporated into a hollow needle, which is inserted into body tissue. After insertion, the hollow needles, which merely serve as import aids, are pulled out of the tissue again, and only the sensors remain in the body tissue. US 5,591,139 also discloses an implantable microneedle system, by means of which substances can be removed from living tissue for diagnostic purposes. In this case, an etched three-dimensional substrate is used.

One of the main advantages of continuous measurement systems is that even quite brief periodic fluctuations in glucose concentration (time courses) can be detected in connection with food intake and physical activity. This is very important for the "establishing" of diabetes control in a person with diabetes.

However, the implantable sensors known from the prior art are extremely costly in terms of the design and manufacture thereof. Assuming that these sensors are disposable and can be used only for a short time (typically about one week), it becomes clear that the methods used in the prior art sensors do not meet such requirements for disposable items. Thus, for example, an elaborate microstructuring method is required for the production of the sensor known from US 5,591,139, in particular a lithographic method. However, such methods are incompatible with the production of low-cost disposables. For the production of the sensor known from US 6,892,085 B2, complex structuring methods are also

required, since the electrode pads have to be carefully constructed. Given the small size of these electrodes, lithographic methods are also required, which in turn increases the cost of manufacturing such sensors.

Also, lithographic methods, in particular the etching of metal layers associated with these methods, are not always as reliable as is required for the manufacture of medical devices. In particular, there may be isolated occurrences that individual electrodes are still connected to each other by "bridges" or bars, so that the functionality of the sensors may be slightly impaired or even completely prevented due to manufacturing problems. Another disadvantage of the sensors known from the prior art, as they emerge for example from US 6,892,085 B2 and US 5,591,139, consists in the use of a hollow needle or in the use of a capillary tube.

Instead of the previously described implantable sensors, in which microstructuring methods, such as, for example, a lithographic method, are used for constructing the electrode pads, implantable sensors can be designed in wire form, as known, for example, from WO 90/10861. WO 90/10861 A1 discloses a sensor system whose individual wires are embedded in an insulating mass. The active measurement surfaces are the respective end faces of the wires within a plane exposed by a separation process or the like. The sensor system according to WO 90/10861 A1 is reusable and is used in an appropriate measuring device. The sample is applied to the previously exposed ends of the wires within the measuring device (*in vitro* measurement).

US 4,805,624 discloses an elongated wire-shaped working electrode of an electrochemical sensor, which is accommodated in a glass rod. In addition to the working electrode, the electrochemical sensor known from US 4,805,624 comprises a reference electrode and a counter electrode, which, however, are spirally wound around the working electrode enclosed by the glass rod. This electrochemical sensor comprises a special electrolyte that is not represented by the bodily fluid. The glucose to be detected diffuses through a membrane, which closes off a hollow cylinder into which the electrolyte is taken up, into the interior of a measuring cell.

The prior art solutions discussed above are in contact with a body tissue only within a very limited range. The electrode arrangement, usually comprising a working electrode, a counter electrode and a reference electrode, is very limited in site, i.e., only able to register meaningful results in a very small area of the body tissue. The function of the sensors known from the prior art, including implantable sensors, can be disrupted by local tissue inhomogeneities, such as wound effects or fat deposits. Furthermore, sensor membrane properties, particularly according to US 4,805,624, have a negative effect on the measured values. The electrode pads known from US 6,892,085 B2 and US 5,591,139 have electrodes adjacent to one another in one plane, in which the required miniaturisability is considerably limited, depending on the microstructuring method selected. The disadvantage of the sensors known from the prior art, including implantable sensors, is to be seen in the fact that low-cost manufacturing processes required for a large-scale production that could be used in the context of a mass production cannot be used.

An implantable sensor with electrodes helically wound around a rod is described in US 2005/0143635.

Object of the invention

The object of the invention is to provide a sensor which can be produced simply and inexpensively by means of a reliable production method and which avoids the disadvantages of the sensors and methods known from the prior art.

Presentation of the invention

The object is achieved by the invention with the characteristics of the independent claims. Advantageous further embodiments of the invention can be found in the dependent claims.

The solution proposed according to the invention therefore proposes an electrochemical sensor for determining a concentration of at least one analyte in a medium, in particular in a body tissue and/or a bodily fluid. The electrochemical

sensor is preferably designed in such a way that it can be implanted in a body tissue and/or introduced subcutaneously. For this purpose, therefore, at least the exposed sensor surface is preferably designed to be biocompatible, so that in particular, no cell toxins can diffuse into the body tissue or come into contact with the body tissue.

The analyte may be, for example, glucose, lactate, hormones or other analytes which play a role in medicine, in particular. Alternatively or additionally, however, the electrochemical sensor can also be used for measuring other types of analytes.

A basic idea of the invention is to design the electrochemical sensor in such a way that an arrangement of at least two thin wires forms an electrochemical measuring cell. The arrangement of thin wires at the same time establishes the electrical connection to a suitable set of measuring electronics. The analyte concentration is then measured by electrochemical (for example amperometric) measuring methods between the at least two electrodes, a working electrode and a counter electrode, in particular by means of a DC voltage. A reference electrode for the currentless measurement of the working electrode potential can additionally be used.

In order to achieve the most compact possible construction of the electrochemical sensor, the individual electrodes of the electrode arrangement are substantially parallel at least in one section, preferably exactly parallel (i.e., an angle deviation from the parallels of preferably not more than 5°, particularly preferably not more than 1°), aligned with each other and insulated against each other by an insulation profile. In this way, more favourable properties of the electrochemical sensor can be achieved, since the sensor has good homogeneity along the longitudinal extent thereof. In particular, the cell width of the sensor (i.e., thickness of the layers, electrode spacing, etc.) has high uniformity and low tolerances.

The electrode arrangement comprises at least two electrodes, which are at least one working electrode and at least one further electrode, wherein the at least one further electrode should in particular comprise at least one counter electrode and/or at least one reference electrode. In the electrochemical sensor proposed according to the invention, the working electrode and the at least one further electrode are

separated from one another by the insulation profile. In addition, there can be a direct partial embedding of the electrodes in an insulating material. In the electrochemical sensor proposed according to the invention, the insulation profile of the electrochemical sensor is represented by an electrically non-conductive material, such as a plastic material.

For the definition of the terms "insulation profile" and "insulating", reference can be made to the embodiments below. Accordingly, direct contact of the electrodes with each other should be avoided. Naturally, any insulation is only conditionally perfect, i.e., provided with an infinite resistance. Currents that do not flow through a junction between the electrodes and the electrolytes are usually referred to as leakage currents and falsify the actual electrochemical measurement. Leakage currents are formed by the connected electronics, the plug connection and in the sensor body itself. Leakage currents should preferably be lower by a factor of 1000 than the actual sensor current.

The electrochemical sensor proposed according to the invention can be advantageously developed according to the invention in a wide variety of ways. The described advantageous further embodiments can be used individually or in combination with one another.

The electrochemical sensor proposed according to the invention has at least one coating electrically contacting the at least one working electrode. While the at least one working electrode is preferably made of a material suitable for electrochemical purposes, such as gold, silver, palladium, platinum or carbon, the wire representing the counter electrode may remain uncoated and may also be made of any of the aforementioned materials suitable for electrochemical purposes. If a reference electrode is implemented on the electrode arrangement of the electrochemical sensor proposed according to the invention, this is preferably an ion electrode of the 2nd. kind, which is preferably made of a silver wire coated on the surface with silver chloride.

An electrode is defined as an interface between a 1st order conductor (charge

transport by electrons in metal) and a 2nd order conductor (charge transport by ions in an electrolyte). For the electrodes (1st order conductors in contact with 2nd order conductors), preferably no materials should be used that passivate (form insulating oxide layers) on the surface, such as aluminium, for example. The working electrode and counter electrodes are redox electrodes, so preferably no materials (1st order conductors) which corrode (i.e., dissolve) at a given polarisation are used for these electrodes.

Due to the configuration of the at least one working electrode used and the at least one counter electrode used within the scope of the proposed electrode arrangement for an electrochemical sensor according to the invention, a slim design of the electrochemical sensor becomes possible. This particular geometrical shape permits the parallel placement of the at least one working electrode parallel to the at least one counter electrode, whereby the effect of the tissue inhomogeneities described on the measurement result which is generated by the electrochemical sensor is considerably reduced. Through the design of the electrode arrangement proposed according to the invention as a three-dimensional geometry, the diameter of the compact sensor can be kept very small. Due to the lateral surface of the electrode arrangement with at least one working electrode and at least one counter electrode, the electrode area necessary for the signal height can be provided.

In a preferred embodiment, the electrochemical sensor proposed according to the invention comprises three wire-shaped electrodes, which are insulated from each other by an insulation profile in Y-geometry. The insulation profile with Y geometry is preferably in the form of a plastic extruded profile and, as will be described in more detail below, can be used to particular advantage in large-scale production in the manufacture of the electrochemical sensor proposed according to the invention. An insulation profile in Y geometry offers the advantageous possibility of providing three receiving compartments for receiving the at least one working electrode, the at least one counter electrode and the optionally used reference electrode for measuring the working electrode potential. The plastic extruded profile, preferably in Y geometry, which forms the insulation profile, gives the electrochemical sensor sufficient mechanical stability and tensile strength. This facilitates the handling of

the electrochemical sensor to a not inconsiderable extent, even for inexperienced users. The sensor may be used, for example, in conjunction with an insertion aid (e.g., with a needle pulled under the skin, the needle being removed again). The sensor should therefore have a certain tensile strength for this purpose. At the same time, however, it should be flexible, so that if the surrounding tissue deforms (through moving or pressing of the skin), the sensor in the tissue will not cause a wound (which could cause the sensor to give incorrect readings, for example). These properties are ensured by the preferred Y geometry.

The electrode arrangement of the electrochemical sensor proposed according to the invention may be provided with a coating for the immobilisation of reactive constituents. This coating for the immobilisation of reactive constituents can be applied to the individual electrodes, i.e., at least one working electrode, the at least one counter electrode and optionally the at least one reference electrode, or to the finished electrode package which includes the insulation profile. The electrode arrangement of the electrochemical sensor proposed according to the invention can comprise, in addition to the electrodes and the insulation profile, additional barrier layers, which can be, for example, layers of a polymer, in particular of an insulating polymer. Examples of suitable polymers are polyester, polyethylene, polypropylene or polyurethane. Other insulating polymers can also be used, wherein reference can again be made to the above description with regard to the term "insulating".

The immobilisation medium coating of the electrode package or of the individual electrodes of the at least one working electrode, the at least one counter electrode or the at least one reference electrode for the immobilisation of reactive constituents is advantageously a membrane layer which has a partial permeability to the at least one analyte. The membrane layer may have a permeability to glucose, lactate and/or other analytes to be detected. The membrane layer with which the electrode package or the individual electrodes mentioned can be coated should advantageously be impermeable to auxiliary chemicals used in the electrochemical measuring method, for example to enzymes used which are applied to one or more of the mentioned electrodes and in some cases have toxicity, and should not enter the body tissue and not contaminate it.

The membrane layer to be applied for the immobilisation of reactive constituents which, for example, surrounds the electrode arrangement in the form of a jacket or surrounds the individual electrodes of the electrode arrangement, the at least one working electrode, the at least one counter electrode and the at least one reference electrode in the form of a jacket. The applied immobilisation medium coating may comprise, for example, a polyurethane. A multi-layer membrane layer construction is also possible. Here, the application of, for example, an immobilisation medium coating containing polyurethane with a coating method such as the dipping method, a spray method or ring nozzle coating can be used.

The electrode arrangement for the electrochemical sensor can be embodied in various ways. As described above, the at least two electrodes comprise at least one working electrode and at least one further electrode, which has at least one counter electrode and at least one reference electrode.

In particular, the at least one counter electrode should be designed in such a way that the counter electrode permits an electrochemical redox reaction which allows a flow of current through the entire measuring cell. If, for example, an electrode reaction supplies electrons, the redox reaction at the other electrode should discharge the equivalent number of electrons. The actual redox reactions can be completely independent of each other. This redox reaction should preferably not limit the current such that the detection reaction at the working electrode is no longer graduated over the entire concentration range (in the case of only two electrodes and an amperometric measurement method). In a three-electrode arrangement with a fed-back reference electrode measuring section, the total cell voltage required to maintain the counter electrode redox reaction should not exceed the dynamic control range of the control electronics.

A counter electrode and a reference electrode may also be designed as a common electrode. The individual electrodes of the electrode arrangement can be coated with enzymes or other chemical adjuvants, each of which is specifically selected depending on the analyte to be detected. For example, for the detection of glucose,

glucose oxidase (GOD) can be used, which converts glucose to gluconolactone. The released charge carriers are detected in this process. To permit this detection, the overvoltage-reducing, charge-mediating materials are used, which act as a kind of "charge mediator" between the medium and the electrodes. Overvoltage-reducing, charge-mediating materials (such as manganese dioxide) are also referred to as electrochemical redox catalysts.

However, since the constituents of the detection reaction chain of the sensor can be detrimental to health, immobilisation of these constituents is in many cases necessary for use of an electrochemical sensor. For immobilisation, there can, for example, be a covalent bond to the electrode and/or a layer of the electrode, for example a metal layer. This technique can be used in particular for the immobilisation of mediators. Another possibility is to incorporate the constituents completely or partially into an insoluble layer which is insoluble in the liquid surrounding the electrochemical sensor in the implanted state, in particular the bodily fluid. It is also possible to use other types of redox mediators, together with whatever enzymes are suitable for the specific detection of the analytes in question.

In addition to the described embodiment of the at least one working electrode, the at least one reference electrode and/or the at least one counter electrode can also be embodied in various ways. Thus, the at least one reference electrode should have an electrode system with an electrochemical potential which does not change or changes only insignificantly within a working range of the electrochemical sensor. For example, at a typical voltage load, i.e., a voltage between the working electrode and the reference electrode of typically not more than 400 mV, the electrochemical potential of the at least one reference electrode should preferably not change by more than ± 5 mV. In this way it is ensured that the reference electrode acts as a real reference with whose potential the electrochemical potential of the at least one working electrode can be compared. Generally, suitable materials and/or material combinations can be used for the reference electrode. A silver/silver chloride (Ag/AgCl) electrode system has proved to be particularly advantageous. Other electrode systems can also be used in principle.

The at least one counter electrode of the proposed electrode arrangement for the electrochemical sensor proposed according to the invention can be designed in a variety of different ways. The at least one counter electrode is designed to be in wire form in order to obtain an electrode arrangement of slender design. It should be ensured, however, that the at least one counter electrode is designed in such a way that the at least one counter electrode permits an electrochemical redox reaction which allows a flow of current through the entire measuring cell. If oxidation takes place at the at least one working electrode, a reduction should take place at the at least one counter electrode of the electrode arrangement and vice versa. In principle, pure metals, such as platinum, can be used as counter electrodes. However, this has the disadvantage that gas formation typically occurs on such metal electrodes, for example formation of hydrogen or oxygen. Gas formation in aqueous media on precious metals such as platinum occurs, for example, when the redox reactions required for the necessary current transport can only be a water electrolysis, i.e., sufficient concentrations of other redox-active species which can occur within the potentials of water electrolysis are not present in the electrolyte. However, such gas formation is sometimes associated with design difficulties, i.e., the design of the sensor must either be adapted to this gas formation, or such gas formation must be avoided. In this regard, it is once again advantageous to use an electrode system, in particular a redox electrode system, in which gas formation is avoided. In particular, the Ag/AgCl electrode system can advantageously be used in this context. In this system, for example, AgCl is reduced. It can be seen from this that the at least one counter electrode is consumed in the operation of the electrochemical sensor. If the at least one counter electrode is consumed, a gas formation frequently takes place in turn, so that the electrochemical sensor generally has a limited service life in operation. Accordingly, it is also advantageous if the at least one counter electrode of the proposed electrode arrangement is designed to be considerably substantially larger with respect to the actual electrode surface thereof than the at least one working electrode of the electrode arrangement.

The electrochemical sensor proposed according to the invention or an apparatus comprising the electrochemical sensor proposed according to the invention is used

for continuously determining a concentration of at least one analyte in the body tissue and/or a bodily fluid. “Continuous" can be understood to mean, for example, that over a certain measurement period, such as a week, analyte concentrations are determined at regular intervals (for example, every 5 minutes or every hour) or continuously, i.e., with a temporal resolution which is limited only by the temporal resolution of a measuring device. However, a problem exists in the case of continuous measurement in a possible drift of the apparatus which comprises the electrochemical sensor proposed according to the invention over the measurement period. A drift generally occurs when the rate constant of one of the rate-determining steps in the entire reaction chain is changed through use. This may, for example, be a decreasing enzyme activity, which, however, is usually only the case if this determines the reaction rate. If possible, the enzyme should be dosed so that a buffer is present over the storage time and duration of use. A change in the diffusion properties of a membrane during the period of use often has the greatest effect. Another problem is that of the non-linear dependence of the measuring current on the glucose concentration, the function curve changing during storage times and duration of use. Here then, one of the rate-limiting steps is limiting from a certain required turnover starting from a determining glucose concentration. A continuous measurement is usually carried out by first carrying out a reference measurement by means of a "conventional" measuring method, for example the removal of a blood drop and measurement of the blood glucose concentration, which is then compared with the measured value supplied by the implanted sensor. Subsequently, a measurement takes place over the measuring period on the basis of the initial reference measurement.

The invention further proposes an apparatus for determining a concentration of at least one analyte in a medium, in particular a body tissue and/or a bodily fluid. The apparatus proposed according to the invention comprises at least one electrochemical sensor according to the above description and possible embodiments thereof. Furthermore, the at least one apparatus comprises at least one voltage measuring apparatus for measuring a voltage of the at least one working electrode and the at least one reference electrode. Alternatively or additionally, at least one current measuring apparatus for measuring a current

between the at least one counter electrode and the at least one working electrode may be provided. In addition, the apparatus may comprise a control apparatus which is designed in such a way that the current between the at least one counter electrode and the at least one working electrode is regulated, such that the voltage measured between the at least one working electrode and the at least one reference electrode is just equal to a predetermined nominal voltage.

The described electrochemical sensor proposed according to the invention can be used, for example, for continuous determination of a concentration of at least one analyte in the body tissue and/or a bodily fluid. For this purpose, the electrochemical sensor proposed according to the invention can, for example, be implanted, for example as part of the apparatus according to the invention in one of the described embodiments, by piercing into the body tissue. Subsequently, a certain amount of time can be made available to the sensor, within which an at least approximate equilibrium is established in the region of the sensor and the surrounding body tissue. Subsequently, the user can perform a calibration measurement, in which, as described above, by means of a conventional method, an analyte concentration in the bodily fluid is determined, for example, a glucose concentration in a drop of blood. The data thus obtained are transmitted to the apparatus according to the invention, for example by manual input or by electronic data transmission, for example by means of a cable or by means of a wireless connection. As a result, a calibration point is made available to the apparatus and the apparatus according to the invention can compare the inputted measured values with measured values which the implanted sensor delivers. Afterwards, the implanted sensor and the apparatus according to the invention can be used, for example, over a period of one week, wherein, for example, a measurement takes place every 5 minutes or even uninterruptedly. The measured values determined by the apparatus according to the invention can be issued to the patient, for example, or they can also be made available to other systems, for example medication systems. Thus, the apparatus proposed according to the invention may be directly connected to an insulin pump, which adjusts an insulin dosage to the measured blood glucose concentrations. After the measuring time has elapsed, the entire apparatus can be replaced, or only the electrochemical sensor proposed according to the invention can be exchanged

for a new, unused sensor.

Data can also be transmitted in the direction opposite to that described above. For example, the apparatus according to the invention with implanted electrochemical sensor can be wholly or partially worn on the body. Separately from this apparatus or as part thereof (the apparatus according to the invention can be constructed in several parts), a calibration apparatus can be provided (for example, as a separate hand-held device) to carry out the described conventional calibration measurement (also known as "spot monitoring"). This calibration apparatus can, for example, function as a "master" device, to which the data determined with the implanted sensor are transmitted. For example, a data memory, display elements and operating elements can then be provided in the calibration apparatus, and further evaluations of the measured data can be carried out.

Furthermore, a method for producing an electrochemical sensor according to the above description, which is suitable for determining an analyte concentration in a medium, in particular in body tissue and/or a bodily fluid, is described. The method comprises the following steps, wherein the steps need not necessarily be performed in the order reproduced below. Various process steps can also be repeated and performed in parallel, and additional, unlisted process steps can be performed.

The manufacture of the electrode arrangement for the electrochemical sensor proposed according to the invention can be carried out using effective, inexpensive production methods. In a first manufacturing step, the at least one working electrode of the electrode arrangement proposed according to the invention, which is preferably made of a material suitable for electrochemical purposes, such as gold, palladium, platinum, and/or carbon, is coated with a reagent suitable for detecting the analyte. This can be done within a ring nozzle coating, wherein the ring nozzle used in the ring nozzle coating encloses the at least one working electrode with a circular cross-section in a ring shape and can coat the entire surface of the at least one working electrode in one operation. Within this manufacturing step, the at least one working electrode forms a long, endless wire, which can advantageously be coated on all sides and in a uniform film or coating thickness in the context of ring

nozzle coating. After ring nozzle coating of the at least one working electrode has been completed, the coated at least one working electrode passes through a drying station, which is preferably designed as a hollow cylinder, so that the at least one coated working electrode passing through the drying station is dried uniformly.

In a subsequent process step, the at least one, now coated working electrode, optionally the at least one reference electrode and also the at least one counter electrode, which can remain uncoated and be made of a material suitable for electrochemical purposes, such as gold, silver, palladium, platinum or carbon, are brought together. In addition to the aforementioned three electrodes of the electrode arrangement, the insulation profile is also prepared as part of the joining of the three electrodes mentioned. The insulation profile, which may have, for example, a Y or star geometry, is preferably a strand extrusion profile made of plastic, which is produced, for example, by micro-extrusion. If, for example, a strand extrusion profile with Y geometry is used, three receiving pockets are advantageously formed, which can receive the at least one working electrode, the at least one counter electrode and the at least one reference electrode.

After the strand extrusion profile, i.e., the insulation profile, and the at least one working electrode, the at least one counter electrode and the at least one reference electrode are brought together, an electrode arrangement in package form is obtained. This electrode arrangement in package form can be delivered in a subsequent production step by an immobilisation medium coating for the immobilisation of the reactive constituents in the context of a further processing operation, preferably designed as a ring nozzle coating process. The application of the immobilisation medium coating for the immobilisation of reactive constituents, which can preferably be carried out with a ring nozzle coating process for applying the immobilisation medium coating in one operation on the entire circumference according to the electrode package obtained in the previous step, can alternatively also be carried out at the individual electrodes, i.e., the at least one working electrode, the at least one counter electrode and the at least one reference electrode.

After the membrane coating process for applying a membrane to immobilise the reactive components, the resulting electrode arrangement in package form is conveyed to a finishing step. Finishing is understood in the following to mean the separation of the electrode package present in endless form provided with an immobilisation medium coating, the electrode package having the insulation profile which isolates the at least one working electrode, the at least one counter electrode and the at least one reference electrode from one another. The finishing of this electrode arrangement present in endless form is achieved by cutting individual sections of the electrode arrangement in packet form. According to the finishing, variable lengths can be separated off, wherein one end of the electrode arrangement obtained, i.e., a section, for example, can be mounted in a suitable insulation displacement connection. The other end of the severed section can be cast in a form-fit part, which also assumes other necessary functions of an electrochemical sensor, for example for insertion into the body tissue.

Drawing

With reference to the drawing, the invention will be described in more detail below.

The figures show as follows:

Figure 1 shows a cross-section through an insulation displacement connection for electrically contacting the electrode arrangement of the electrochemical sensor according to the invention,

Figure 2 shows a schematic side view of the apparatus proposed according to the invention for determining an analyte concentration in a medium with an insertion head and the insulation displacement connection,

Figure 3 shows an arrangement for coating a single electrode of the electrode arrangement with a reagent medium suitable for detecting an analyte, with a downstream drying station,

Figure 4 shows the joining of the at least one working electrode, the at least one counter electrode, an insulation profile and a reference electrode to form an electrode arrangement,

Figure 4.1 shows a section through the insulation profile,

Figure 5 shows a ring nozzle coating station for applying a membrane permitting an immobilisation of reactive constituents to the electrode arrangement,

Figure 6 shows finishing of the electrode arrangement provided with an immobilisation medium coating,

Figure 7 shows a perspective top view of the electrode arrangement proposed according to the invention,

Figure 8 is a schematic process diagram, and

Figure 9 shows a section of a cross-sectional representation of the surface of a working electrode.

Embodiment variants

The illustration according to Figure 1 shows a section through a plug (designed as an insulation displacement connection in this example), which comprises an electrode arrangement for an electrochemical sensor.

The cross-section through an electrochemical sensor 10 shown in Figure 1 shows an electrode arrangement 16, 18, 20. The electrode arrangement 16, 18, 20 is enclosed by a jacket 12, which can enclose an embedding material 14. The electrode arrangement comprises at least one working electrode 16, at least one counter electrode 18 and at least one reference electrode 20. The electrode arrangement 16, 18, 20 extends in the representation of Figure 1 perpendicular to the plane of the drawing, wherein the at least one working electrode 16, the at least

one counter electrode 18 and the at least one reference electrode 20 run parallel to each other.

The at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 form an electrochemical measuring cell and at the same time the body of the electrochemical sensor 10. The at least one working electrode 16 is made of a material suitable for electrochemical purposes, such as gold, silver, palladium, platinum or carbon. The use of other precious metals or other metals or metal alloys, including in multi-layer arrangement, is possible. The at least one working electrode 16 is coated with a suitable reagent to detect the analyte, as described in more detail below.

The at least one counter electrode 18 is also made of a material suitable for electrochemical purposes, such as gold, silver, palladium, platinum or carbon, and can remain uncoated or even be coated with one or more layers. Again, as an alternative or in addition, as with the other electrodes, it is also possible to use other metals (preferably precious metals) or metal alloys or multi-layer metals. The at least one reference electrode 20 is preferably made of a silver wire, which is covered on the lateral surface thereof with silver chloride. The at least one reference electrode 20 is used for the currentless measurement of the potential of the at least one working electrode.

From the illustration according to Figure 1, it is also apparent that a connector 22 for producing electrical contacting of the at least one working electrode 16, a connector 24 for electrically contacting the at least one counter electrode 18 and an electrical connector 26 for electrical contacting of the at least one reference electrode 20 are constructed on the circumference of the jacket 12 of the electrochemical sensor 10. In the illustration according to Figure 1, the number of connectors 22, 24, 26 corresponding to the number of electrodes 16, 18, 20 is arranged in a circumferential pitch 42, which is 120° in the schematically reproduced exemplary embodiment shown. Depending on the number of individual electrodes used in the electrode arrangement 16, 18, 20, a corresponding number of connectors 22, 24, 26 is provided on the jacket 12 of the electrochemical sensor

10. In the exemplary embodiment illustrated in Figure 1, the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 are electrically contacted via contacting elements 28. The contacting elements 28 may be constructed as insulation displacement contacts which include a cutting edge 30. A pointed end of the wedge-shaped cutting edge 30 constructed on the contacting elements 28 contacts, respectively, the circumferences of the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20. As an alternative to an insulation displacement connection, the ends of the wires can also be exposed and separately soldered, bonded or glued onto an adapter board. This arrangement can then be cast, for example, in a connector housing, for example.

It also emerges from the sectional view of Figure 1 that the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 are insulated against each other by an insulation profile 32. In the illustration according to Figure 1, the insulation profile 32 is formed in Y-geometry, resulting in receiving compartments to accommodate each of the at least one working electrode 16, the at least one counter-electrode 18 and the at least one reference electrode 20. The insulation profile 32 is preferably manufactured as a strand extrusion profile. Instead of the Y-geometry 34 shown in Figure 1, the insulation profile 32 may also have a different configuration, for example X-shaped or T-shaped. A cross-shaped design of the geometry of the insulation profile 32 is also possible. It should be ensured that the geometry 34 of the insulation profile guarantees that the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20, which run parallel to each other, are separated from each other through the insulation profile, for example through the insulation profile 32, by bars.

The insulation profile 32 in Y-geometry 34 shown in section in Figure 1 comprises a first bar 36, which separates the at least one counter electrode 18 from the at least one working electrode 16. A second bar 38 of the insulation profile 32 is used to separate the at least one working electrode 16 from the at least one reference electrode 20, which in turn is separated from the at least one counter electrode 18

of the electrode arrangement 16, 18, 20 by a third bar 40 of the insulation profile 32.

The illustration according to Figure 2 shows an apparatus which includes the electrochemical sensor according to Figure 1.

The schematic illustration according to Figure 2 shows that the electrochemical sensor 10 is part of an apparatus which has an insertion head 60. The insertion head 60 is rounded at the end thereof and has a diameter of preferably < 1 mm, in particular < 500 micrometres and particularly preferably < 50 micrometres. The insertion head 60 is used for subcutaneous insertion of the electrochemical sensor into a body tissue. The insertion head 60 is sealed off from the electrode arrangement 16, 18, 20 by means of a first seal 32, wherein in the representation according to Figure 2 only the at least one working electrode 16 and the at least one reference electrode 20 are shown. The double arrow indicated by reference symbol 70 indicates the direction of movement in the apparatus for determining an analyte concentration in a body tissue or in a bodily fluid.

As an alternative to the method of introduction by means of the insertion head 60 shown in Figure 2, however, other apparatus or procedures are conceivable to introduce the electrochemical sensor 10, in which no insertion head 60 is required. Thus, for example, the electrochemical sensor 10 can be introduced into the tissue via a slotted hollow needle, wherein instead of an insertion head 60, only insulation of the end face of the sensor 10 can be used. Alternatively or additionally, the electrochemical sensor 10 can also be pulled under the skin by means of an insertion aid, for example a needle or a blade. In this case, for example, a form-fit part can be used, which serves as a driver and, when pulling out the insertion aid, does not pull the electrochemical sensor 1 back out therewith. The electrochemical sensor 10 itself, however, should be designed in such a way that, after the end of the use thereof, it can also be removed relatively easily from the tissue.

The apparatus shown in Figure 2 comprises, in addition to the insertion head 60 and the electrode arrangement 16, 18, 20, a connection carrier 64 shown in cross-

section in Figure 1, which, as described above in connection with Figure 1, is preferably designed as an insulation displacement connection. The connection carrier 64 ensures the electrical contacting of the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20. The connection carrier 64 has a circumference 66, to which the connectors 22, 24, 26 shown in Figure 1 for electrically contacting the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 are electrically contacted. As already mentioned in connection with Figure 1, the electrical contacting elements 28 are preferably formed as wedge-shaped elements comprising cutting edges 30 which each contact the peripheral surface of the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20. The apparatus according to the representation in Figure 2 further comprises an evaluation unit which evaluates the signals which are transmitted via the at least one working electrode 16 and the at least one counter electrode 18 and carries out a determination of the analyte concentration in the body tissue or in a bodily fluid and displays this directly to the user.

For the sake of completeness, it should be mentioned that the cutting line I-I corresponds to the section through the electrochemical sensor 10 shown in Figure 1. Between the connection carrier 64, which can be preferably embodied as a form-fit part, and the electrode arrangement 16, 18, 20, there is a second seal 68. Depending on the finishing of the electrode arrangement 16, 18, 20, comprising at least one working electrode 16, at least one counter electrode 18 and at least one reference electrode 20, there can be different lengths of the electrode arrangement 16, 18, 20 between the first seal 62 to the insertion head 60 and the second seal 68 to the connection carrier 64. According to the finishing of the length of the electrode arrangement 16, 18, 20, a more or less deep subcutaneous insertion of the electrochemical sensor into a body tissue can be carried out to determine an analyte concentration. Following the solution according to the invention, the at least one working electrode 16, the at least one working electrode 18 and the at least one reference electrode 20 form the electrochemical measuring cell, which is enclosed by body tissue after insertion of the insertion head 60 and permits detection of an analyte in a body tissue or bodily fluid. Due to the design of the at

least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 as wire-shaped components, the electrode arrangement 16, 18, 20 has a very elongated surface. Thus, due to the high, elongated electrode surface, the electrochemical detection occurs in a large area of tissue. As a result, local inhomogeneities (e.g., insulating fat cells) have less of an impact on the total current, as it is incorporated over a larger area. High power turnover is also typically associated with high glucose consumption. This can lead to depletion in the tissue and thus to false lows in the determined measurements. The aim is therefore not to choose the electrode surface, but at the same time to capture a lot of space in the tissue. This goal is achieved in particular by long, thin wires. Alternatively or additionally, glucose consumption can also be curbed by a thicker immobilisation layer. The thinner the design of the electrode package, the lower, usually, the disrupting interactions with the body tissue (e.g., cell growth or wound healing).

The illustration according to Figure 3 shows a first manufacturing step of the electrode configuration, as shown in Figures 1 and 2 on the basis of an electrochemical sensor.

The electrochemical sensor 10 proposed according to the invention is characterised by a manufacturing process which allows the use of individual production steps advantageous for large-scale production. The components of the electrochemical sensor 10 are essentially the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20, as well as the insulation profile 32. The single or multi-layer coating for producing an at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 are described in more detail below.

The at least one working electrode 16 of the electrode arrangement 16, 18, 20 is coated with a suitable reagent for detecting the analyte in a body tissue that is to be determined. This coating step is carried out as shown in Figure 3 in the context of ring nozzle coating 82. For this purpose, the at least one working electrode 16 moves in the conveying direction 80 through a ring nozzle 84. The ring nozzle 84

comprises a cavity 92 which is filled with a reagent medium 86. The reagent medium 86 is conveyed into the cavity 92 of the ring nozzle 84 by a delivery pump 90. Because the cavity 92 of the ring nozzle 84 is acted upon by the reagent medium 86, the at least one working electrode 16 in wire form is coated on the surface 94 thereof with the reagent medium 86 in one operation while passing through the cavity 92 of the ring nozzle 84 in the conveying direction 80. The reagent medium 86 may be, for example, a mixture of manganese dioxide (glass soap), graphite and GOD (glucose oxidase), which catalytically converts glucose into gluconolactone. The at least one working electrode 16 leaving the ring nozzle 84 in the conveying direction 80, after passing through an outlet opening 88 of the ring nozzle 84, has a coated surface 94 which is formed by the reagent medium 86. In a drying station 100 downstream of the ring nozzle 84 in the conveying direction 80 of the at least one working electrode 16, the film of the reagent medium 86 is dried on the surface 94 of the at least one working electrode 16, before following the manufacturing steps described below.

Figure 4 shows the joining of the at least one coated working electrode with the at least one counter electrode, the at least one reference electrode and the insulation profile present in strand form.

The at least one working electrode 16 coated with a reagent medium 86 as part of the coating step 82 as shown in Figure 3 is conveyed to a merging station 130 as at least one coated working electrode 110. The at least one, preferably uncoated counter electrode 18 and the at least one reference electrode 20 are also conveyed to the merging station 130. Furthermore, the insulation profile 32, which is preferably produced as a strand extrusion profile and which has the Y geometry 34 shown in Figure 4.1, is also conveyed to the merging station 130. In the merging station 130, the at least one, now coated working electrode 16, the at least one, for example, uncoated or coated, counter electrode 18 and the at least one reference electrode 20 are grouped around the insulation profile 32 in such a way that the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 are insulated from each other. The merging station 130 leaves an electrode arrangement which comprises at least one coated working

electrode 16, at least one, preferably uncoated counter electrode 18, at least one reference electrode 20 and the insulation profile 32. The electrode arrangement 16, 18, 20 leaving the merging station 130 constitutes an electrode package 132.

The illustration according to Figure 5 shows a further manufacturing step to which the electrode package according to Figure 4 is conveyed after the merging. Figure 5 shows that the electrode package 132, which comprises the at least one coated working electrode 110, the at least one preferably uncoated counter electrode 18 and the at least one reference electrode 20, is conveyed to an immobilisation medium coating 140. In the context of the immobilisation medium coating 140 shown in Figure 5, for immobilising reactive constituents, an immobilisation medium 142 is, for example, applied to the electrode package 132 entering a ring nozzle 146 as shown in Figure 5. As a result, the electrode package is additionally insulated and/or toxic components (for example, the GOD acting as a cytotoxin) are prevented from diffusing into the body tissue. The outside of the electrochemical sensor 10, which comes into contact with the body tissue, should be biocompatible (i.e., not be rejected by the body). This is another particularly preferred property of the immobilisation medium 142. Alternatively or additionally, an additional layer can be applied, which ensures this additional property of biocompatibility. The other materials used, which come into contact with the body tissue, such as materials for insulation in the connector area and at the insertion end, should have appropriate biocompatible properties or be appropriately coated.

The ring nozzle 146 used in the context of the immobilisation medium coating 140 comprises a cavity 150, which has an outlet opening 148 and is filled with an immobilisation medium 142. The cavity 150 of the ring nozzle 146 is continuously filled with the immobilisation medium 142, so that the entire surface of the electrode package 132 entering the cavity in the conveying direction 80 is wetted by the immobilisation medium 142. At the outlet opening 148 of the ring nozzle 146, the lateral surface of the electrode package 132, which enters the ring nozzle 146 in the conveying direction 80, is provided with a coating of immobilisation medium 142. The conveying direction of the electrode package 132 is designated by the reference symbol 144 in the illustration according to Figure 5. Reference symbol

152 denotes the electrode package 132 coated with the immobilisation medium 142.

Instead of the electrode package 132 entering the ring nozzle 146 in the conveying direction 144 in Figure 5, which comprises the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20, which are insulated from one another by the insulation profile 32, the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 can be conveyed individually to the immobilisation medium coating 140. Via the immobilisation medium coating 140, which can be applied according to Figure 5, contact takes place between the at least one coated working electrode 110 and the at least one, preferably uncoated, counter electrode 18 and the body tissue or the bodily fluid, whereby the presence of a particular analyte is to be determined. The illustration according to Figure 6 shows a finishing step.

According to the finishing 160 shown schematically in Figure 6, the coated electrode package 152 provided according to the above manufacturing steps, which is coated on the circumference with the immobilisation medium 142, for example, is finished into individual sections 164. The finishing 160 is preferably carried out by a transverse cutting of the coated electrode packet 152. Different lengths 162 of the finished sections 164 can be adjusted, depending on the intended use.

Insertion head 60 shown in Figure 2, together with first seal 62, is fastened to sections 164 produced in accordance with finishing 160 at one end, and the connection carrier 64 shown in Figure 2, to which connections 22, 24, 26 are connected, is fastened thereto at the other end according to the number of electrodes of the electrode package 132. Thus is obtained the apparatus not shown in full length in Figure 2, which includes an electrochemical sensor 10. The electrochemical measuring cell of the electrochemical sensor 10 is formed by the lateral surface of the layer of the immobilisation medium 142 applied in the context of the immobilisation medium coating 140. This layer of immobilisation medium 142 represents the boundary of the electrochemical measuring cell and the contact surface with which the electrochemical sensor 10 is in contact with the body tissue

or bodily fluid.

The illustration according to Figure 7 shows a perspective view of the electrode arrangement of the electrochemical sensor 10.

From the illustration according to Figure 7, it can be seen that the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 are separated from one another via the insulation profile 32. The insulation profile 32 having a Y-geometry 34 in the representation according to Figure 7 comprises the first bar 36, the second bar 38 and the third bar 40. The first bar 36 and the second bar 38 delimit a first receiving compartment 174, in which the at least one working electrode 16 is received. The at least one working electrode 16 has a coating with a reagent medium 86 of a reagent for detecting the analyte in the body tissue or in the bodily fluid. The illustration according to Figure 7 shows that the immobilisation medium 142 can be applied to this reagent medium 86. In the variant of the electrode arrangement 16, 18, 20 of the electrode package 132 shown in Figure 7, the immobilisation medium 142 is applied to the lateral surface of the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20. As described above in connection with Figure 5, the entire electrode package 132 emerging from the merging station 130 according to Figure 4 can also be coated as a whole with the immobilisation medium 142, which then constitutes the embedding material 14 shown in Figure 1.

The perspective illustration according to Figure 7 also shows that the second bar 38, with the third bar 40 of the insulation profile 42, delimits a third receiving compartment 178 in which the at least one reference electrode 20 is accommodated in the exemplary embodiment according to Figure 7. Finally, as shown in Figure 7, the third bar 40 and the first bar 36 of the insulation profile 32 define a second receiving compartment 176, in which the at least one counter electrode 18 of the electrode arrangement 16, 18, 20 is located. The illustration according to Figure 7 shows that a diameter 170 of the reference electrode is of the order of magnitude of approximately 100 µm, while with reference symbol 172 the sum of the diameters of the at least one reference electrode 20, the at least one counter electrode 18 and

the material thickness of the third bar 40 of the insulation profile 32 is designated. The distance 172 as shown in Figure 7 has a length of the order of about 250 µm.

From the stated dimensions of the electrode arrangement 16, 18, 20 according to the perspective view in Figure 7, it is apparent that the proposed electrode arrangement 16, 18, 20 of the electrochemical sensor 10 proposed according to the invention has very compact dimensions, which is based on to the parallel arrangement of the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 in the receiving compartments 174, 176 and 178 of the insulation profile 32.

The illustration according to Figure 8 shows a schematic representation of the manufacturing method for producing the electrochemical sensor, in particular the electrode arrangement.

It can be seen from the flow diagram according to Figure 8 that, in the context of the ring nozzle coating 82, the at least one working electrode 16 is coated with the reagent medium 86, which represents a reagent suitable for detecting the analyte. The reagent medium 86 is dried in the subsequent drying step within the drying station 100, which reagent medium is located on the surface 94 of the at least one working electrode 16 after the ring nozzle coating 82,. The at least one working electrode 16, which is now coated with the reagent medium 86 on the surface 94, is then joined with the preferably uncoated, at least one counter electrode 18, the at least one reference electrode 20 and the insulation profile 32 preferably produced by the strand extrusion process. The joining takes place in a merging station 130. The electrode package 132 obtained from the merging station 130 is subsequently subjected to an immobilisation medium coating 140. Within the scope of the immobilisation medium coating 140, it is possible both to apply the immobilisation medium 142 to the electrode package 132 obtained in the merging station 130 as a whole and consequently to embed the electrode package 132 in the immobilisation medium. In addition, it is also possible to coat the at least one working electrode 16, the at least one counter electrode 18 and the at least one reference electrode 20 separately and to combine these coated individual

electrodes in the merging station 130.

As part of the finishing 160 that follows the immobilisation medium coating 140, there is a separation of either the coated electrode package 152 or the combined individually coated individual electrodes 16, 18 and 20. As part of the finishing 160, sections 164 are produced, which may be formed in different lengths 162, the length 162 depending on the application of the electrode arrangement for use in an electrochemical sensor 10.

Figure 9 schematically shows a section of an electrode surface of a working electrode 16 in a sectional view. The working electrode has a gold wire 180 in this example. The gold wire 180 is coated with a reagent medium 86 according to the method shown in Figure 8. The reagent medium in this example consists of three different components: conductive carbon particles 182, manganese dioxide particles 184, GOD particles or GOD conglomerates 186 and a binder polymer 188. The binder polymer 188 ensures the processing properties of the reagent medium in the undried state. The viscosity and/or surface tension of the reagent medium 86 is adjusted by selection of the binder polymer 188 so that it can be processed well in the "wet" (i.e., undried) state by ring nozzle coating 82 and forms a homogeneous, uniform layer that adheres well to the gold wire 180. At the same time, the binder polymer is selected such that it can be dried at moderate temperatures without, for example, GOD 186 being destroying by heat in this drying step. Examples of a suitable binder polymer 188 also include mixtures, for example, mixtures of polymers with various solvents.

Furthermore, Figure 9 also shows the layer of the immobilisation medium 142. This surrounds the reagent medium 86 and prevents bodily fluid (symbolically denoted here by 190) from coming into direct contact with the manganese dioxide particles 184 and with the GOD particles 186 and prevents GOD from diffusing into the bodily fluid 190. At the same time, oxygen and glucose as the analytes to be detected can diffuse out of the bodily fluid 190 through the layer of the immobilisation medium 142 and thus reach the reagent medium 86.

Finally, in Figure 9, the reaction used to detect glucose 194 in bodily fluid 190 is represented symbolically by a "reaction arrow" 192. Glucose 194 is oxidised to gluconolactone via the enzyme GOD 186 and then oxygen is reduced to H_2O_2 by the enzyme GOD 186. Subsequently, the H_2O_2 is catalytically oxidized by the manganese dioxide 184 and the electrons are transferred to the efferent gold wire 180 via the carbon particles 182 which are in contact with the manganese dioxide 184. The potential of the gold wire 180 (or the entire working electrode 16) influenced in this way can be detected in the manner described above, for example by an amperometric measurement, and the concentration of glucose in the bodily fluid 190 can be deduced therefrom.

PATENTKRAV

1. Elektrokemisk sensor (10) til bestemmelse af en koncentration af mindst én analyt i et medium, nærmere bestemt et kropsvæv og/eller en kropsvæske, hvor den elektrokemiske sensor (10) omfatter et isoleringselement (32) og mindst to elektroder (16, 18, 20), hvor de mindst to elektroder (16, 18, 20) omfatter mindst én arbejdselektrode (16) og mindst én yderligere elektrode (18, 20), især mindst én tællerelektrode (18) og/eller mindst én referenceelektrode (20), hvor de mindst to elektroder (16, 18, 20) er udformet mindst delvist som trådformede elektroder, der strækker sig i det væsentlige parallelt med hinanden med perifere elektrodeoverflader, hvor de mindst to elektroder (16, 18, 20) strækker sig langs et isoleringselement (32) med en profileret udførelsesform, **kendetegnet ved,** at isoleringselementet (32) med en profileret udførelsesform omfatter mindst to beholderrum (174, 176, 178) til de mindst to elektroder (16, 18, 20) og at den mindst ene arbejdselektrode (16) er mindst delvist omsluttet, fortrinsvis helt omsluttet, af et reagensmedium (86) til bestemmelse af en koncentration af mindst én analyt i et medium, nærmere bestemt et kropsvæv og/eller en kropsvæske.

2. Elektrokemisk sensor ifølge krav 1, kendetegnet ved, at de mindst to elektroder (16, 18, 20) er helt omsluttet eller delvist omsluttet af mindst ét lag af et immobiliseringsmedium (142), enten individuelt eller i form af en elektrodepakke (132).

3. Elektrokemisk sensor ifølge krav 2, kendetegnet ved, at immobiliseringsmediet (142) har en mindst delvis gennemtrængelighed for den mindst ene analyt.

4. Elektrokemisk sensor ifølge krav 2 eller 3, kendetegnet ved, at immobiliseringsmediet (142) omfatter en polyurethan og/eller et yderligere polymermateriale.

5. Elektrokemisk sensor ifølge krav 1, kendetegnet ved, at isoleringsprofilen (32) er fremstillet af en polymer, især en elektrisk isolerende polymer.

6. Elektrokemisk sensor ifølge et hvilket som helst af de foregående krav, kendetegnet ved

- at den mindst ene arbejdselektrode (16) omfatter mindst ét elektrodemateriale, der er egnet til elektrontransmissionsreaktion og til strømtransport, hvilket elektrodemateriale fortrinsvis er grafitpartikler på guld, der omfatter mindst ét materiale fra gruppen, der indbefatter guld, sølv, palladium, platin og kulstof, og
- at elektrodematerialet er omsluttet af mindst ét reagensmedium (86), der omfatter mindst ét materiale fra gruppen, der indbefatter: en elektro-redoxkatalysator til

reduktion af overspænding, især MnO_2 (manganoxid), et hjælpestof, et enzym som specifik katalysator for en analyt, der skal detekteres, især glucoseoxidase (GOD), kulstof, et polymerbindingsmateriale,

- hvor det mindst ene reagensmedium (86) fortrinsvis er omgivet mindst delvist, nærmere bestemt helt, af et immobiliseringsmedium (142).

7. Elektrokemisk sensor ifølge et hvilket som helst af de foregående krav, kendetegnet ved, at der er tilvejebragt mindst én tællerelektrode (18), hvor den mindst ene tællerelektrode (18) fortrinsvis er fremstillet af et materiale, der er egnet til elektrokemisk måling, fra gruppen, der indbefatter guld, sølv, palladium, platin eller kulstof.

8. Elektrokemisk sensor ifølge et hvilket som helst af de foregående krav, kendetegnet ved, at der er tilvejebragt mindst én referenceelektrode, hvor den mindst ene referenceelektrode (20) fortrinsvis omfatter Ag og er belagt på overfladen med AgCl, og er omsluttet mindst delvist, fortrinsvis helt, af et immobiliseringsmedium (142).

9. Apparat (10, 60, 64) til bestemmelse af en koncentration af mindst én analyt i et medium, nærmere bestemt et kropsvæv og/eller en kropsvæske, omfattende mindst én elektrokemisk sensor (10) ifølge et hvilket som helst af de foregående krav, omfattende mindst ét spændingsmålingsapparat og/eller mindst ét strømmålingsapparat til måling af en spænding og/eller en strøm mellem den mindst ene arbejdselektrode (16) og den mindst ene tællerelektrode (18) og/eller den mindst ene referenceelektrode og fortrinsvis yderligere omfattende et indsættelseshoved (60) og/eller et indsættelseshjælpemiddel.

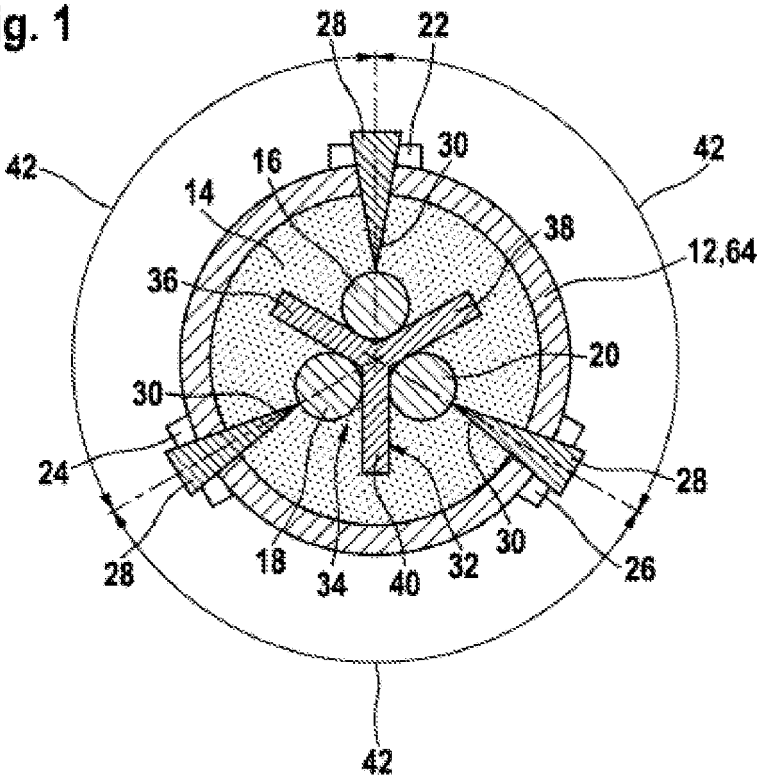
10. Apparat ifølge krav 9, kendetegnet ved, at den elektrokemiske sensor (10) er forbundet til et elektrisk stik (64), fortrinsvis et elektrisk stik (64), der er udformet som en formsluttende del.

11. Apparat ifølge krav 10, kendetegnet ved, at det elektriske stik (64) omfatter mindst to elektriske stik (22, 24, 26) til de mindst to elektroder (16, 18, 20) til elektrisk kontakt med deres overflader.

12. Apparat ifølge krav 10, kendetegnet ved, at det elektriske stik har en isoleringsforskydningsforbindelse og/eller et indsættelseshjælpemiddel og/eller en hul nål.

13. Anvendelse af et apparat (10, 60, 64) ifølge et hvilket som helst af de foregående krav vedrørende et apparat (10, 60, 64) til kontinuerlig detektering af en koncentration af mindst én analyt i et medium, nærmere bestemt et kropsvæv og/eller en kropsvæske.

Fig. 1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14
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32
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26
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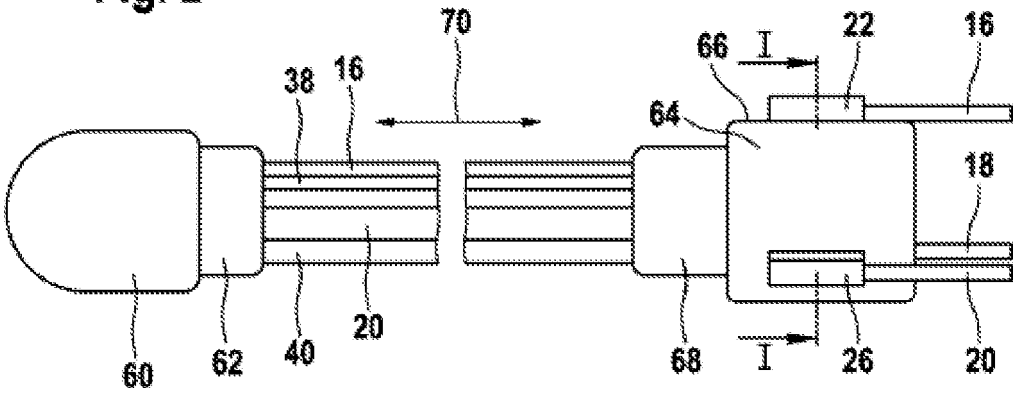
Fig. 2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20

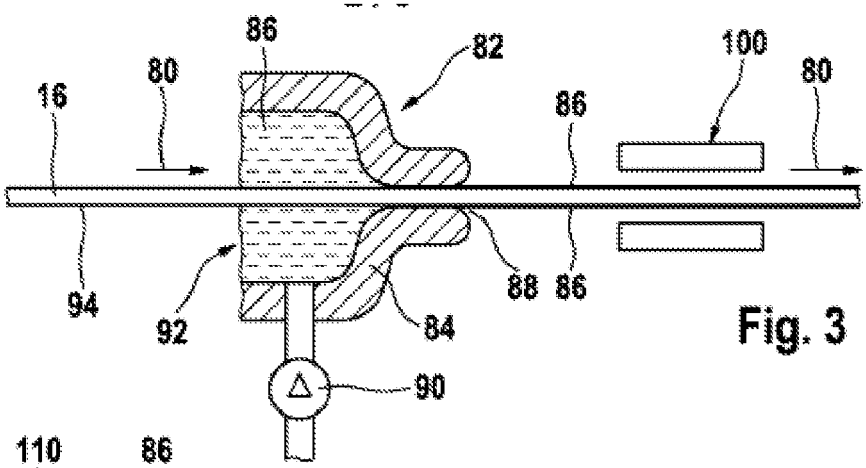


Fig. 3

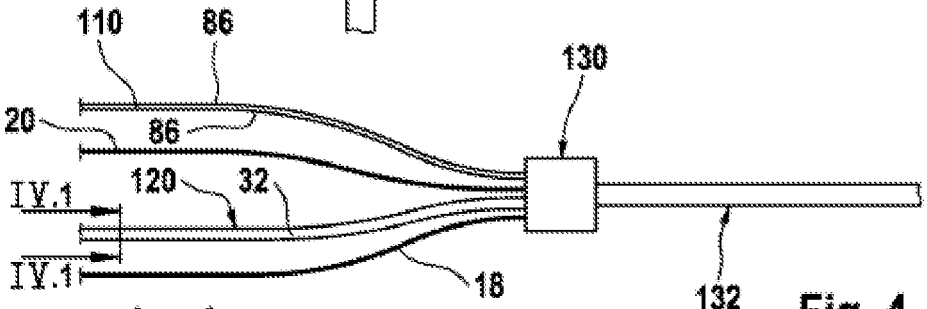


Fig. 4

Fig. 4.1

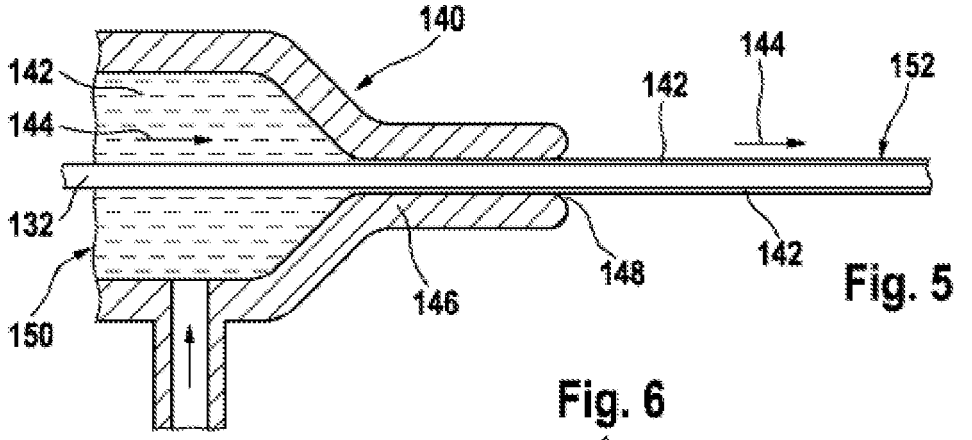
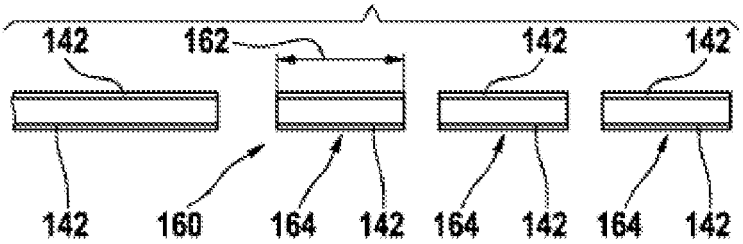


Fig. 5

Fig. 6



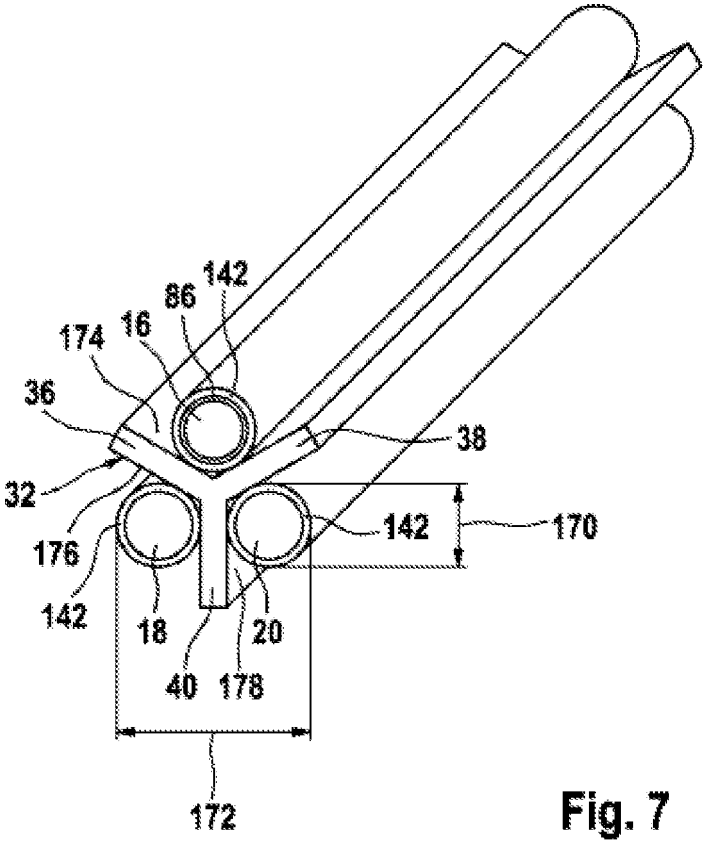


Fig. 7

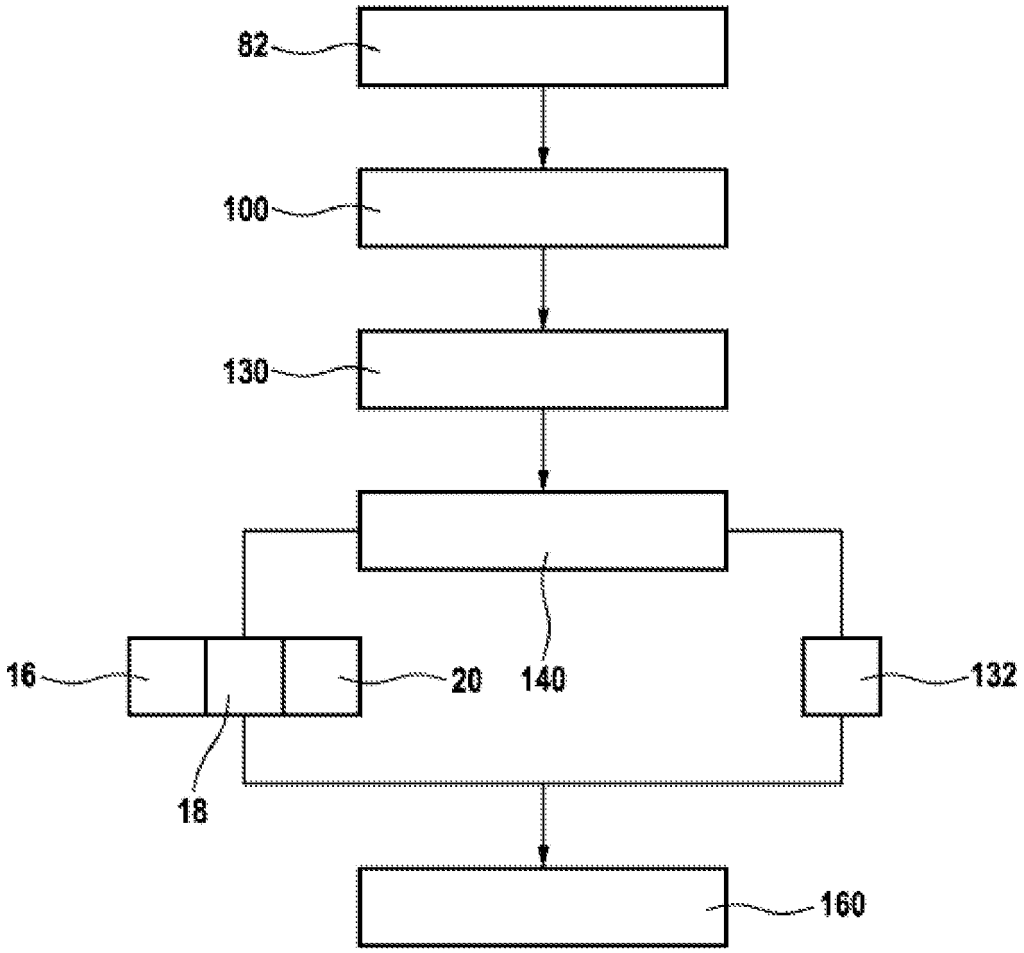


Fig. 8

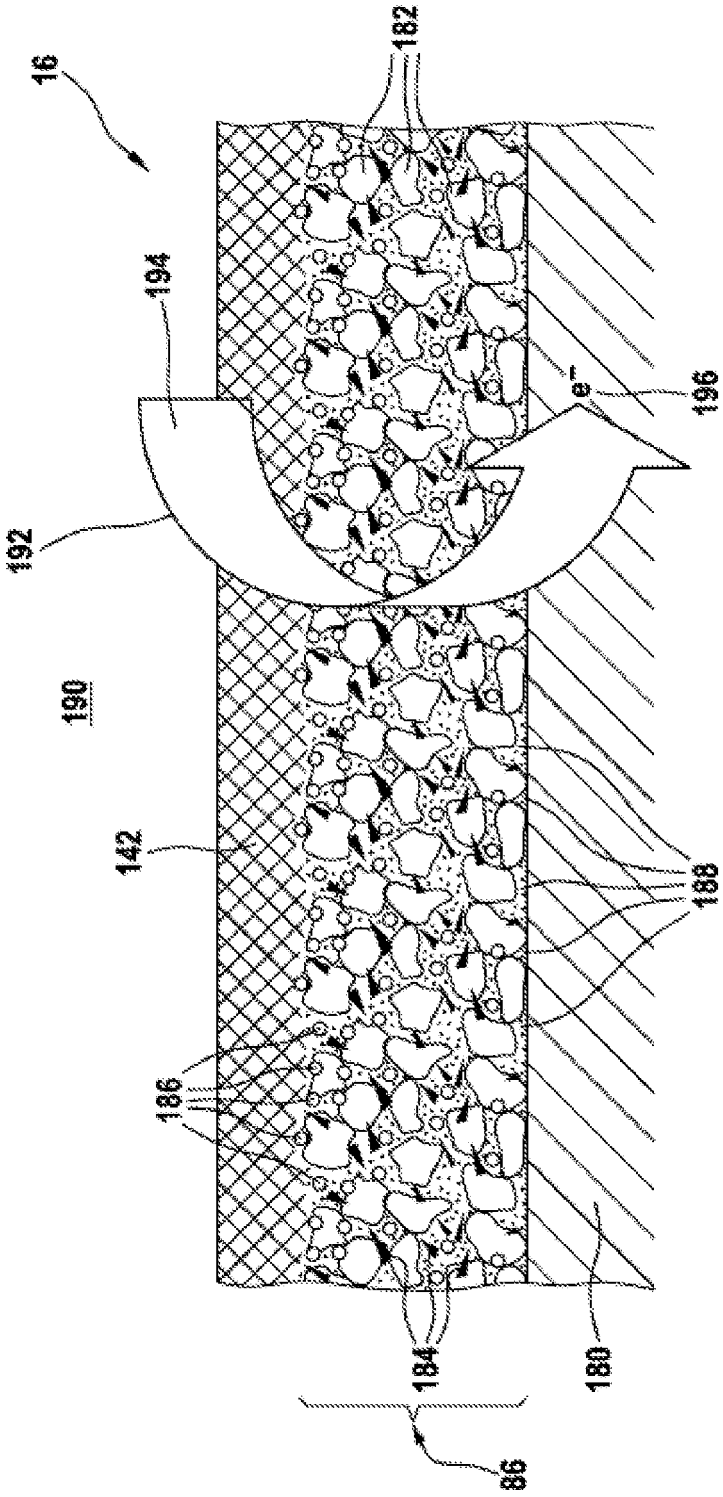


Fig. 9